

Allogeneic Cardiac-Derived Stem Cells for Patients Following a Myocardial Infarction

Grant Award Details

Allogeneic Cardiac-Derived Stem Cells for Patients Following a Myocardial Infarction

Grant Type: Disease Team Therapy Development - Research

Grant Number: DR2A-05735

Project Objective: The goals of this project are to manufacture cell products (CAP-1002) for clinical use and to complete a randomized, double-blind, placebo-controlled Phase II study of the safety and efficacy of intracoronary delivery of allogeneic cardiosphere-derived cells (CDC) in patients with a myocardial infarction and ischemic left ventricular dysfunction. Patients considered for participation in the study are those who had a myocardial infarction between 30 days and one year prior to treatment.

Investigator:

Name: Rachel Smith
Institution: Capricor, Inc
Type: PI

Name: Michelle Kreke
Institution: Capricor, Inc
Type: Co-PI

Disease Focus: Heart Disease, Heart failure

Human Stem Cell Use: Adult Stem Cell

Award Value: \$14,405,857

Status: Active

Progress Reports

Reporting Period: Year 1

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Reporting Period:	Year 2
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Reporting Period:	Year 3
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Reporting Period:	OM #1
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Reporting Period:	OM #2
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Reporting Period:	OM #6
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Grant Application Details

Application Title:	Allogeneic Cardiac-Derived Stem Cells for Patients Following a Myocardial Infarction
Public Abstract:	<p>The proposed research will demonstrate both safety and efficacy of a heart-derived stem cell product in patients who have experienced a heart attack either recently or in the past by conducting a mid-stage clinical trial. A prior early-stage trial showed that the product can repair damaged portions of the heart after a heart attack in ways that no commercial therapy currently can. Damaged areas turn irreversibly into scar tissue after the initial event, which can predispose a person to future events and lead to an ongoing worsening of general and heart health. Data from the early-stage trial suggest that treatment with the heart-derived cell product under development can turn scar tissue back into healthy heart muscle. The planned mid-stage trial will hopefully confirm that finding in a larger patient group and provide additional data to support the safety profile of the product. The product is manufactured using heart tissue obtained from a healthy donor and can be used in most other individuals. Its effect is thought to be long-lasting (months-years) although it is expected to be cleared from the body relatively quickly (weeks-months). Treatment is administered during a single brief procedure, requiring a local anesthetic and insertion of a tube (or catheter) into the heart. The overriding goal for the product is to prevent patients who have had a heart attack from deteriorating over time and developing heart failure, a condition which is defined by the heart's inability to pump blood efficiently and one which affects millions of Americans. Successful completion of the proposed mid-stage trial would lead next to a final, confirmatory trial and then to the application process by which permission to market the product is obtained from the Food and Drug Administration. The end result could be an affordable stem cell therapy effective as part of a treatment regimen after a heart attack.</p>

Statement of Benefit to California:

The manufacturer of the heart-derived stem cell product under development is a California-based small company who currently employs 7 California residents. Five new local jobs will be created to support the proposed project. Three medical centers located in California will participate in the proposed mid-stage clinical trial. The trial will hopefully bring notoriety to both the company and the medical centers involved while at the same time provide a novel therapeutic option for the many citizens of California afflicted with heart disease. Recent statistics place California among the 50% of states with the highest death rates for heart disease. Therefore, a successfully developed cell product could have a meaningful impact on the home population. Furthermore, as manufacturing needs grow to accommodate the demands of early commercialization, the company anticipates generating 100+ new biotech jobs.

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